510(k) Summary

MAY 2 9 2013

510(k) Number:

K124056: FREND™ PSA Plus on the FREND™ system

Summary Preparation Date:

December 28, 2012

Submitted by:

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DOCRO, Inc. (CRO assigned as contact with the FDA)

Proprietary Names:

For the assay: FREND™ PSA Plus

For the instrument: FREND™ system

Common Names:

For the assay: Quantitative PSA immunoassay

For the instrument: Bench-top fluorometer with microprocessor

Regulatory Information:

Regulation section:

866.6010 Tumor Associated Antigen Immunologic Test System
862.2560 Fluorometer

Classification:

Class II

Panel:

Immunology

Product Code(s):

For the assay: LTJ Tumor Associated Antigen Immunologic Test System
For the instrument: KHO Fluorometer

Predicate Device: TOSOH ST AIA-PACK PA (P910065/S004)

Intended Use:

The FREND™ PSA Plus performed on the FREND™ system, is a quantitative *in* vitro diagnostic test which measures total Prostate Specific Antigen (PSA) in human serum and plasma. The NanoEnTek FREND™ PSA Plus is designed for *in vitro* DIAGNOSTIC USE ONLY for the quantitative measurement of total Prostate Specific Antigen (PSA) in human serum, heparinized plasma, and EDTA plasma using the FREND™ System. This device is indicated for the serial measurement of total PSA in serum, heparinized plasma and EDTA plasma to be used as an aid in the management of patients with prostate cancer.

The FREND™ PSA Plus is indicated for use in clinical laboratories upon prescription by the attending physician as an aid to clinicians in managing patients with prostate cancer.

The information provided from this test may supplement decision-making and should only be used in conjunction with routine monitoring by a physician and the use of other diagnostic procedures. Because of the variability in the effects of various medications used in the treatment of prostate cancer, clinicians should use professional judgment in the interpretation of PSA results as an indicator of disease status.

Technological Characteristics:

The FREND™ PSA Plus is a rapid fluorescence immunoassay that measures prostate specific antigen (PSA) in human serum and in lithium heparin and EDTA plasma using the FREND™ system. The FREND™ PSA Plus is intended for use as an aid for prostate cancer management. The FREND™ PSA Plus Test is a single use fluorescence immunoassay designed to quantify the concentration of total PSA in serum and lithium heparin and EDTA plasma samples. The specimen is added by the operator to the sample inlet with a transfer pipet, allowing the appropriate volume of sample (30 µL) to be delivered into the FREND™ PSA Plus Test Cartridge. The Cartridge is then placed into the FREND™ System, which is programmed to begin analysis once the sample has reacted with the reagents. The reaction and analysis time is approximately 6 minutes. The PSA quantification is based on the amount of fluorescence detected by the FREND™ System at the FREND™ PSA Plus Test Cartridge window. A higher level of fluorescence is indicative of a higher PSA concentration. In other words, the magnitude of the fluorescent signal is directly proportional to the amount of total PSA in the sample.

Material Provided - FREND™ PSA Plus - Catalog Number FRPS 025

- 25 FREND™ PSA Plus cartridges - The Test Cartridge is a disposable plastic device that houses the reagents and contains an opening where the sample is applied. Once the sample is applied, it will mix with the reagents and travel towards the detection area via capillary action. The sample is dropped into the specimen inlet located on the top left corner of the Test Cartridge. Sample and reagents interact before being analyzed by the FREND System fluorescence reader. The shelf-life of FREND PSA Plus cartridges is 12 months. One Cartridge contains:

Monoclonal anti-PSA1	48 ± 9.6 ng
Monoclonal anti-PSA2	144 ± 28.8 ng
Fluorescent particle	2.4 ± 0.48 µg

- 30 Disposable pipette tips (micro-pipettor optional)
- 1 FREND™ PSA Plus Code Chip - The QC Code Chip contains data to ensure the performance of the FREND System's power, optical, and software systems when the QC Cartridge is inserted into the System. The QC Code Chip is inserted into the code chip port at the rear of the System. Each QC Code Chip is specific to its accompanying QC Cartridge. Each time a new lot is used, the PSA Code Chip that corresponds to that new lot must be inserted into the instrument and the previous PSA Code Chip must be removed.. If the PSA Code Chip and the PSA Cartridge are not from the same lot, an error message will appear.
- 1 FREND™ PSA Plus Package Insert
- 1 Product Certificate
- QC Case – Storage box for the QC Cartridge and QC Code Chip
- Optional FREND™ System Pipettor – device sheathed in a disposable single use plastic tip used to transfer samples to the Cartridge.
- Adaptor & Power cable – used to supply power to the System
- FREND™ System User Manual
- FREND™ System Quick Manual
- USB drive 1.1
- Optional printer - Results of the test can be printed out using the optional printer. Otherwise, they are displayed on the screen.

Commercially available controls from a variety of manufacturers are available that contain total PSA as a measured analyte. These controls are not provided with the assay cartridge.

The FREND™ System is not provided with the kit but is required for utilization of the FREND™ PSA Plus assay cartridge.

FREND™ System is a bench top fluorescence reader containing a touchscreen user interface. The System has a slot that accepts the FREND™ PSA Plus Test Cartridge (which contains the reagents and sample), and is programmed to analyze the Test when the sample has fully reacted with the on-board in cartridge reagents. Results of the test are displayed on the screen and can be printed on an optional printer through the RS232C interface.

Performance Data Summary – Analytical Testing

To determine the analytical validity of the FREND™ PSA Plus, a series of studies have been performed as described below.

1. **Estimates of imprecision**: intra-assay, inter-assay and complex imprecision analyses were generated at three sites including the NanoEnTek, Inc. facility as well as at CLIA licensed facilities in the US. Imprecision was found to be acceptable at all three sites on all three lot numbers. The magnitude of the imprecision is not significantly different than that seen with other devices of this type.

   Precision data was determined as described in the CLSI protocol EP5-A2. Three clinical samples were assayed in replicates of two at two separated times per day for twenty days using a single lot cartridge. Results are shown below in table format. All elements of this testing process met the specifications set. Repeatability and Within-laboratory precision on samples with measured concentrations from 0.1 to 1.0 ng/mL was less than 15%. At concentrations >1.0 ng/mL but < 25 ng/mL, Repeatability and Within-laboratory precision was less than 10%.

Clinical Sample Precision

Sample	Mean PSA	Repeatability		Between-run		Between-day		Within-laboratory	
	(ng/mL)	SD	CV(%)	SD	CV(%)	SD	CV(%)	SD	CV(%)
1	0.186	0.026	14.20	0.005	2.9	0.004	2.3	0.027	14.6
2	2.757	0.221	8.0	0.132	4.8	0.071	2.6	0.268	9.7
3	16.625	1.407	8.5	0.000	0.0	0.449	2.7	1.477	8.9

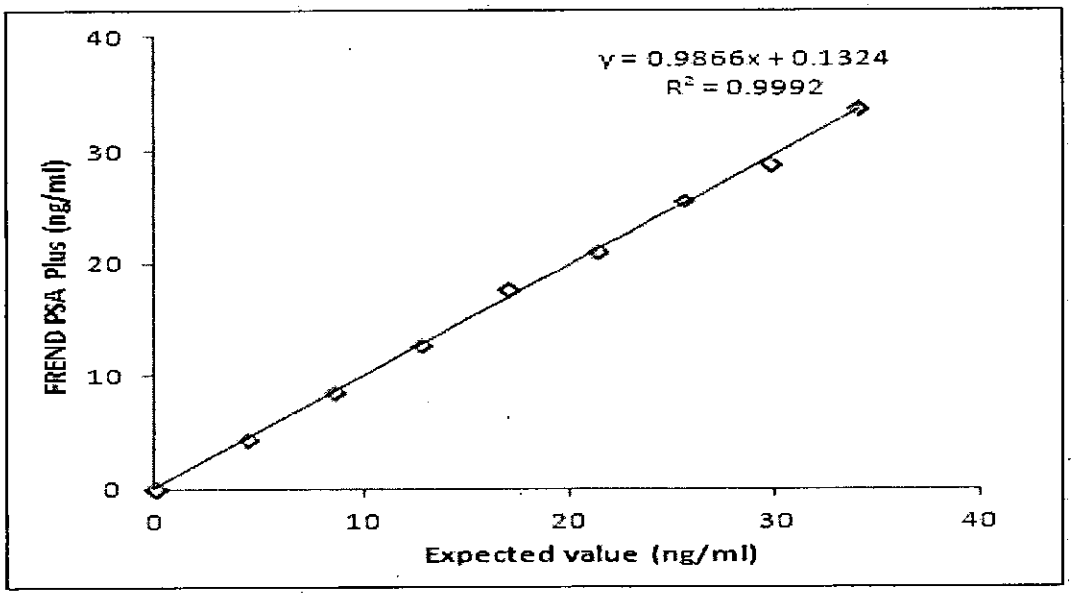
Three different lots of FREND™ PSA Plus were evaluated at three geographically diverse sites. Four replicates each of Material A, Material B, and Material C and two replicates of QC 1, QC 2 and QC 3 were evaluated in each of two runs performed for five days at each site. A total of 40 results on each material were generated at each of the three sites yielding a grand total of 120 replicates of each material. The data was analyzed using a CLSI format from EP5-A2 for an ANOVA analysis. Instrument-to-Instrument is the same as Site-to-Site in this scenario. As can be seen from the table below, the largest source of variation is the cartridge which would be the expected result. The FREND™ PSA Plus cartridge is a single use cartridge that contains all the reagents within the cartridge necessary to support the reactions.

%CV by Material for Multi-Site, Multi-Lot Imprecision						
	Material					
Variation Source	MAT A (0.29 ng/mL)	MAT B (3.67 ng/mL)	MAT C (18.33 ng/mL)	QC 1 (0.30 ng/mL)	QC 2 (2.93 ng/mL)	QC 3 (20.25 ng/mL)
Site-to-Site	3.50%	1.57%	1.67%	3.47%	1.61%	2.06%
Day- to- Day	0.00%	0.99%	1.21%	0.00%	0.00%	0.00%
Lot- to- Lot	9.12%	3.16%	7.01%	6.08%	4.30%	6.00%
Inter- cartridge	18.45%	6.81%	7.94%	20.03%	6.17%	7.49%
Total	20.87%	7.74%	10.79%	21.22%	7.69%	9.81%

2. Dilution Linearity & Recovery:

To demonstrate the linearity of the assay, a serum sample pool with an elevated total PSA (34 ng/mL) was diluted to a total of seven levels according to the dilution protocol outlined in CLSI-EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach. In addition, a "neat" sample (no dilution) and a "zero" sample were also be run. At each dilution level, the samples were tested in 6 replicates to determine the observed value of PSA. Percent recovery was calculated by comparing the observed PSA result with the expected value. Recoveries within + 10% of the expected results for the overall mean recovery at concentrations above 1.0 ng/mL for each sample were considered acceptable proof of this performance goal.

Dilution Linearity FREND™ PSA Plus



No.	Dilution	TEST 1	TEST 2	TEST 3	TEST 4	TEST 5	TEST 6	MEAN (ng/mL)	SD	CV%	Expected Value	% Recovery
Blank	0.000	0.00	0.00	0.10	0.00	0.00	0.10	0.033			0.0	
1	0.125	4.63	4.65	4.08	4.27	4.59	4.26	4.413	0.241	5.5	4.3	103.8
2	0.250	8.85	8.65	9.24	8.18	8.67	7.74	8.555	0.526	6.1	8.0	106.9
3	0.375	13.30	12.33	12.71	13.91	12.61	11.58	12.740	0.802	6.3	12.8	99.9
4	0.500	18.34	16.89	18.22	16.07	17.56	18.57	17.608	0.972	5.5	17.0	103.6
5	0.625	21.44	22.49	19.39	19.32	20.67	22.78	21.015	1.490	7.1	21.3	98.9
6	0.750	23.78	25.42	27.13	26.88	24.91	25.93	25.675	1.255	4.9	25.5	100.7
7	0.875	28.04	34.33	27.12	29.51	27.36	26.38	28.790	2.913	10.1	29.8	96.8
High	1.000	39.98	35.22	31.74	27.43	28.32	40.09	33.797	5.561	16.5	34.0	99.4

3. **Spiked Recovery:** a serum pool from females (initial tPSA concentration < 0.01 ng/mL) was spiked with three (3) different known levels of PSA across the range of the assay (0.1 to 25 ng/mL). After spiking, samples were assayed during the same run before and after spiking. The percentage of tPSA recovered was compared to the theoretical amount spiked into the samples. Recoveries within 10% of the expected result for the overall mean recovery for a given sample were considered acceptable proof of this performance goal.

Spiked Recovery FREND™ PSA Plus

Concentration Added (ng/mL)	Observed Concentration (ng/mL)	Recovery (%)
1.08	1.06	98.3
	1.09	100.7
	1.04	96.7
4.34	4.42	101.8
	4.35	100.3
	4.27	98.4
12.81	13.58	106
	12.04	94

	11.82	92.3
25.53	24.26	95
	24.67	96.6
	26.90	105.4

The percentage recovery ranged from 92.3% to 105.4%. The results are within the acceptance region.

4. **Analytical Sensitivity (Limits of Detection or LOD/LOQ)**: Determination of the limit of detection/limit of quantitation was performed according to procedures outlined in CLSI-EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantitation. In the determination, 5 samples without PSA (blank samples) and 5 samples with a low PSA concentration were tested in the assay in 12 replicates for each sample. The 95th percentile value for the blank samples was 0.04 ng/mL. The 5th percentile value for the low PSA samples was 0.055 ng/mL. At a PSA value of 0.1 ng/mL, there were no blank samples (without PSA) labeled as detected by the assay and 50% of low PSA sample values (LOD samples) had a PSA value below 0.1 ng/mL. The LOD/LOQ limit as determined by this testing is 0.1 ng/mL PSA.

5. **High Dose Hook Effect Testing (Prozone Detection)**: The presence of high dose hook effect was tested by analyzing a concentrated sample of purified PSA antigen both neat and on dilution. No High Dose Hook effect was seen in samples with a PSA concentration as high as 1200 ng/mL.

6. **Interfering Substances and Assay Specificity**: Prostatic acid phosphatase and kallikrein (not otherwise described) were evaluated for potential cross-reactivity with the FREND PSA Plus at 10 ng/mL and 15 ng/mL respectively utilizing the instructions recommended by CLSI protocol EP7-A. No significant cross-reactivity was found.

   Interference studies on endogenous serum substances were performed using the FREND PSA Plus according to the recommendations in the CLSI protocol EP7-A. Interference is defined to be recovery outside of 15% of the known specimen mean concentration. Lack of interference (recovery from 85% to 115% of the expected) is considered acceptable performance. The following describes the interferents tested and the maximum concentration without interference at the total PSA concentrations evaluated:

   - Added hemoglobin (up to 500 mg/dL) does not interfere with the assay. Average recovery when added to serum containing tPSA at 1.0 and 4.0 ng/mL was 97.25%.
   - Added conjugated bilirubin (up to 20 mg/dL) does not interfere with the assay. Average recovery when added to serum containing tPSA at 1.0 and 4.0 ng/mL was 98.2%.

- Added gamma globulin (Total Protein) up to 5.0 g/dL does not interfere with the assay. Average recovery when added to serum containing tPSA at 1.0 and 4.0 ng/mL was 106.3%.
- Added triglyceride up to 3 grams/dL does not interfere with this assay. Average recover when added to serum containing tPSA at 1.0 and 4.0 ng/mL was 101.5%.

No interference was found from endogenous materials such as bilirubin, triglycerides, hemoglobin, or added protein at a level above what is found in the usual clinical laboratory specimen.

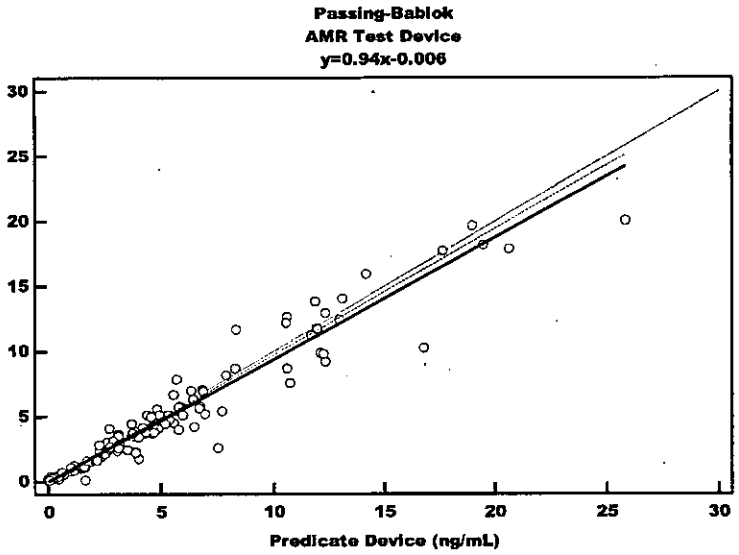
Drugs commonly given to patients with prostate cancer and some common over-the-counter medications were also tested using CLSI protocol EP7-A.

Drug Interference Testing FREND™ PSA Plus

Substance	Interferent Concentration tested	Average % Recovery
flutamide	10 µg/mL	94.5%
Diethylstilbestrol (DES)	5 µg/mL	103.8%
goserelin	40 ng/mL	103.2%
tamsulosin	100 ng/mL	98.85%
acetaminophen	250 ng/mL	100.45%
acetylsalicylic acid	600 µg/mL	95.85%
leuprolide	275 ng/mL	101.5%
ibuprofen	500 µg/mL	102.25%
finasteride	250 ng/mL	93.6%
docetaxel	10 µg/mL	114.45%

No interference outside the acceptable recovery range (100 ± 15%) was found.

7. **Method comparison**: Comparison studies were done in the DOCRO, Inc. laboratory testing facility, Orion Laboratory, Inc., at the time the clinical samples enrolled for this study were evaluated. The predicate device and the FREND™ system were run at the same time, side-by-side on the bench so samples were tested simultaneously using the same aliquot of sample. Regression analysis was performed on the data pairs obtained from prostate cancer samples taken at a single point (n = 85) and the earliest sample from 75 subjects undergoing serial monitoring for prostate cancer. Any samples reading above either of the linearity limits of the predicate or proposed assay was diluted and the final result determined by multiplying the dilution factor by the answer obtained on that dilution. Statistics were generated on the samples from prostate cancer subjects (n=160). For those results whose tPSA was less than 25 ng/mL, the linearity limit of the FREND™ PSA Plus assay, comparison was performed using Passing-Bablok regression analysis.



The two methods compared well within the specifications usually accepted in the clinical laboratory.

8. **Sample Matrix Comparison Study**: The FREND™ PSA Plus designates multiple matrices as being acceptable sample types. Lithium heparin and EDTA plasma are specified in addition to serum as appropriate sample types. Matrix comparison studies were performed in which the various matrices above plus sodium citrate were compared with respect to the PSA result in a serum matrix. Deming regression and Passing-Bablok were performed. Concentrations of PSA across the measuring range were used. 36 matched sets were collected, aliquoted, frozen and then run once all collections were completed.

   To determine the statistical relationship between the PSA concentrations of the plasma specimens and that of the serum specimen, linear regression and Passing-Bablok regression analyses were performed. Equivalence of repeatability in duplicate runs for all matrices and equivalence of variance between serum and each of three different plasma matrices in three partitions were also evaluated. An assessment of the repeatability of variance for each matrix type was performed to ensure that variation in serum samples was equivalent to variation in each plasma type. Analysis showed that EDTA heparin, lithium heparin and serum are all acceptable matrices. Sodium citrate showed unacceptable performance.

9. **Reagent Stability Studies:** Real time stability studies of the FREND PSA Plus Test Cartridge were conducted over 15 months on three different lots. The Test Cartridges were either stored at 2 – 8°C or at room temperature. At each of three month intervals, the Test Cartridge was assayed with five standard specimens. The results using both the refrigerated and the room temperature stored cartridges for the five standard specimens yielded results with a %CV of less than 10% meeting the acceptance criteria. Reagent

studies showed that the cartridges for FREND™ PSA Plus are good for at least one year from date of manufacturer if stored appropriately as directed.

10. Performance Data Summary – Clinical Testing

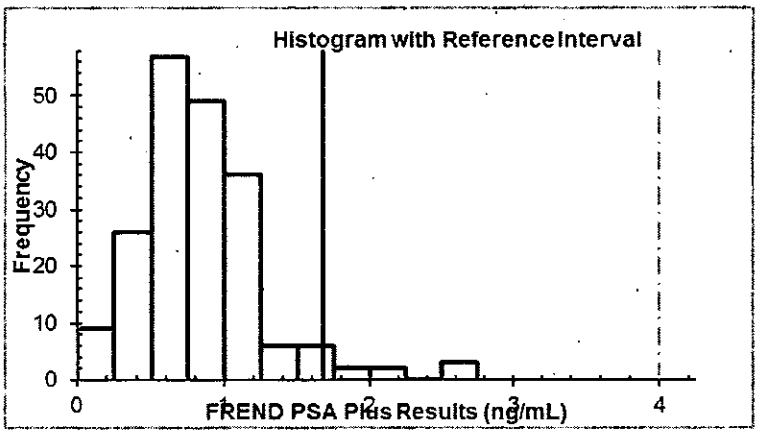
A total of 1219 evaluable clinical serum samples were assessed during this study. Results were obtained on both the FREND™ PSA Plus and the predicate device. Sample distributions across various cohorts of samples: Normal, Benign and Malignant, were studied. Testing of ambulatory male subjects fifty years old and older who reported themselves as healthy without any known illnesses, diseases or conditions was performed. The cohorts shown in the following table were assembled to determine the distribution of values in benign diseases that may be co-existent in patients with confirmed prostate cancer. Prospectively collected stored samples were utilized for this study.

Cohort	Number
Benign prostate disease (BPH, prostatitis, etc.)	104
Benign Diseases of the GI tract	107
Subjects with Diabetes of any type	97
Cardiovascular Disease/Hypertension	102
Total	410

The following patient cohorts were assembled to determine the distribution of PSA values in patients with known malignancies (a mixture of treated and untreated are represented).

Cohort	*Number*
Lung/Liver Cancer	52
Gall Bladder/Gastric/Pancreatic Cancer	31
Prostate Cancer (Divided by Gleason Score)	85
Colorectal Cancer	89
Other Cancers	45
Total	302

Normal male cohort: For the FREND PSA Plus assay in normal men age 50 years or older the following graph shows the distribution of PSA in these normal men.



The 95th percentile value using the FREND PSA Plus assay is well below a value of 4.0 ng/mL. The upper 95th percentile value for the same cohort of men using the predicate assay was similar.

Distribution of Serum FREND™ PSA Plus Concentrations in Healthy, Benign and Various Malignant Disease States

	N	0 – 4.0 ng/mL	4.1 – 10.0 ng/mL	10.1 – 20 ng/mL	20.1 – 40 ng/mL	>40 ng/mL
Healthy Subjects	**196**					
Men ≥ 50 yrs.	196	100%	0%	0%	0%	0%
Benign Disease/Cond*	**410**					
Benign Prostate	104	56.73%	25.96%	11.54%	3.85%	1.92%
Diabetes	97	95.88%	3.09%	1.03%	0.00%	0.00%
HTN/Heart Disease	102	95.10%	4.90%	0.00%	0.00%	0.00%
Benign GI	107	94.4%	4.67%	0.00%	0.93%	0.00%
Malignant Diseases*	**302**					
Prostate Cancer**	85	40.00%	38.82%	12.95%	2.35%	5.88%
Gleason Score 5-6	43	51.16%	44.19%	2.38%	2.38%	0%
Gleason Score 7	31	35.48%	38.72%	19.35%	0%	6.45%
Gleason Score 8-9	11	9.09%	18.18%	36.36%	9.09%	27.27%
Lung/Liver Cancer	52	98.08%	0%	1.92%	0%	0%
GB,Gastric,Pancreatic	31	100%	0%	0%	0%	0%
Colorectal Cancer	89	94.38%	4.49%	1.13%	0%	0%
Other Cancers	45	97.78%	2.22%	0%	0%	0%
TOTAL Subjects	**908**					

*Treated and untreated subjects

**Serial samples are not included in this cohort.

Performance between the two assay systems did not show any clinically significant differences.

Serially monitored subjects: As an important part of the clinical studies performed to characterize the FREND™ PSA Plus, serial samples collected longitudinally from patients previously diagnosed with prostate cancer and treated in a variety of ways over the clinical

course of their disease (including prostatectomy, radioactive seeds, external beam radiation, chemotherapy, hormone therapy alone or in combination) were assayed for tPSA with the FREND™ PSA Plus on the FREND™ system. The same samples were also measured for tPSA by the predicate PSA method.

For each point to point in a sample serial set, the change in the tPSA concentration was compared to the change in the clinical status of the patients as measured by other laboratory tests, patient interviews, physical examinations, and imaging studies of a variety of types.

These changes in the tPSA marker concentration were defined as significant or not by multiplying the overall %CV of the assay at the midrange (as determined by the test imprecision study) by a factor of 2.5 to define a percentage change difference higher than would be expected because of assay imprecision. For the FREND™ PSA Plus assay with an overall mid-range %CV of 8%, significance was set at a change in excess of 20%. Any increase in value from one time period to the next that did not exceed 20% was logged as ≤ 20% Change. For the predicate method, significant percentage change was set at a change > 8.5%. This was calculated using that method's published overall mid-range CV of 3.4% x 2.5.

Disease status for the patients was determined by the physician. This Disease Status was used to determine Progression or No Progression from a clinical perspective. The first table below shows the progressions and non-progressions as determined for the FREND™ PSA Plus results for all seventy five subjects compared to the Clinical Status changes. The second table shows the same comparison for the other FDA cleared assay. There are a total of 236 such determinations for each assay.

Point to Point for FREND™ PSA Plus

% Change in PSA Value	Progression	No Progression	Total
Change≥ 20.0%	84	46	130
Change< 20%	25	81	106
Total	109	127	236

Point to Point for Another FDA Cleared PSA Assay

% Change in PSA Value	Progression	No Progression	Total
Change≥ 8.5%	88	45	133
Change< 8.5%	21	82	103
Total	109	127	236

Below is a chart comparing the concordances of the FREND™ PSA Plus assay and the TOSOH ST AIA-PACK PSA.

Concordance FREND™ PSA Plus and TOSOH ST AIA-PACK™ PSA

Concordance	FREND	95% CI*	FDA Cleared PSA	95% CI*
Positive	77.06%	69.02% to 84.85%	80.73%	73.19% to 88.03%
Negative	63.78%	55.30% to 71.97%	64.57%	56.25% to 75.59%
Total	69.92%	63.98% to 75.85%	72.03%	66.10% to 77.54%

*Confidence Intervals are based on 10,000 resamples of the patient data

Based on the 95% confidence intervals, there are no differences between the concordances for the FREND™ PSA Plus assay and TOSOH ST AIA-PACK™ PSA assay. Positive, negative and overall concordances determined on the serial sets of samples for the two methods showed no significant difference in the ability of the assay to mirror the patient clinical status.

Substantial Equivalence

The FREND™ PSA Plus is as safe and effective as the "Predicate Device", the TOSOH ST AIA-PACK PA assay. FREND™ PSA Plus has a similar Intended Use and Indications for Use for monitoring of prostate cancer patients, similar technological and performance characteristics, and principles of operation as its predicate device. The differences between the FREND™ PSA Plus and its predicate device raise no new issues of safety or effectiveness. Performance data, analytical and clinical, demonstrate that the FREND™ PSA Plus is as safe and effective as the "Predicate Device".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NANOENTEK INC.
C/O JUDITH E. LOEBEL
DIRECTOR, CLINICAL AND REGULATORY AFFAIRS
DOCRO INC.
1 JACKS HILL ROAD SUITE A & B
OXFORD CT 06478

May 29, 2013

Re: K124056
Trade/Device Name: FREND™ PSA Plus on the FREND™ System
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: II
Product Code: LTJ, KHO
Dated: May 18, 2013
Received: May 24, 2013

Dear Ms. Loebel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k124056

Device Name: FREND™ PSA Plus on the FREND™ system

Indications For Use:

The FREND™ PSA Plus as performed on the FREND™ system, is a quantitative in vitro diagnostic test which measures total Prostate Specific Antigen (PSA) in human serum and plasma. The NanoEnTek FREND™ PSA Plus is designed for *in vitro* DIAGNOSTIC USE ONLY for the quantitative measurement of total Prostate Specific Antigen (PSA) in human serum, heparinized plasma, and EDTA plasma using the FREND™ System. This device is indicated for the serial measurement of total PSA in serum, heparinized plasma and EDTA plasma to be used as an aid in the management of patients with prostate cancer.

The FREND™ PSA Plus is indicated for use in clinical laboratories upon prescription by the attending physician as an aid to clinicians in managing patients with prostate cancer.

The information provided from this test may supplement decision-making and should only be used in conjunction with routine monitoring by a physician and the use of other diagnostic procedures. Because of the variability in the effects of various medications used in the treatment of prostate cancer, clinicians should use professional judgment in the interpretation of PSA results as an indicator of disease status.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k): k124056